Citation:

Kelly, SAM. Summerbell, CD. Brynes, A. Whittaker, V. Frost, G. Wholegrain cereals for coronary heart disease. Cochrane Database of Systematic Reviews. 2, 2007

Study Design:

Meta-analysis; systematic review (Cochrane)

Class:

M - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To review the current evidence from RCTs that assess relationship between the consumption of wholegrain foods and effects on CHD morality, morbidity and on risk factors for CHD in participants previously diagnosed with CHD or with existing risk factors for CHD.

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Inclusion Criteria:

RCTs that assessed effects of wholegrain foods or diets containing whole grains, over a minimum of 4 wk, on CHD and risk factors. Adults with existing CHD or who had at least one risk factor for CHD (e.g. abnormal lipids, raised BP, overweight status).

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Exclusion Criteria:

Multiple component interventions; interventions which incorporated factors other than wholegrain foods/diets, unless effect of wholegrain foods/diets could be separated from other factors; Studies on foods based only on individual components of grain were not included (oat bran, wheat germ); studies examining effect of high-fiber, dietary fiber, cereal fiber, but where specific effect of wholegrain foods/diets could not be distinguished.

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Description of Study Protocol:

Recruitment

MEDLINE, EMBASE, CINAHL, CENTRAL searches

Design

Data extraction by 2 independent reviewers: general information, trial characteristics, intervention, participants, outcomes, results.

Quality assessment: Cochrane criteria; method of randomization, concealment of allocation; blinding; intention-to-treat analysis;

Blinding used (if applicable)

Intervention (if applicable)

Statistical Analysis

RevMan software:

Chi-squared and I^2 statistic tests for heterogeneity (P<0.01)

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Pooling using weighted mean differences in fixed effects meta-analysis

Sensitivity analysis

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Sensitivity analysis

Description of Study Protocol:

- *Recruitment:* Patients admitted to the Department of Geriatric Medicine of the University Hospital of Dijon between August 1990 and September 1991
- *Design:* RCT.

Intervention (if applicable)

- A baseline assessment of thiamine status was performed on all 70 patients (35 with heart failure and 35 without). Then those who had cardiac failure (N=35) were randomized into either the thiamine-supplemented group (CF1) or the non-supplemented group (CF2)
- 200mg intravenous or intramuscular thiamine per day was given to CF1 for seven days
- Biochemical thiamine assessment was performed on Day Eight, while the clinical and roentgenological assessment was made on both Days Eight and 15.

Statistical Analysis

All data were determined not to be normally distributed. Therefore, quantitative variables were transormed into semi-quantitative variables of the type (low or high) and groups were compared by a Chi-square test for all the variables.

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Data Collection Summary:

Timing of Measurements

N/A

Dependent Variables

- Total-C
- LDL-C
- HDL-C
- TAGs
- Body weight
- CHD mortality, morbidity
- Changes in risk factors

Independent Variables

Whole grain foods/diets

Control Variables

RCTs, concurrently-controlled trials included; meta-analytic techniques; study selection and inclusion in analysis.

Data Collection Summary:

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Timing of Measurements

- *Day Zero (within 24 hours of admission):* For estimation of thiamine status and for the clinical assessment and chest roentgenogram for cardiac function in all patients
- *Day Eight:* Biochemical thiamine assessment, clinical assessment and chest roentgenograms in the cardiac failure patients
- *Day 15:* Clinical assessment and chest roentgenograms in the cardiac failure patients.

Dependent Variables

- *Variable One (thiamine status)*
  - Blood was sampled by venipuncture into an heparinized Venoject evacuated tube
  - The samples were kept in crushed ice
  - Plasma was removed after centrifugation at 1,000xg for 10 minutes at 4°C and the erythrocytes were washed three times with an equal volume of saline
  - Erythrocyte transketolase (ETK) activity and the thiamine pyrophosphate (TPP) stimulation effect (TPPE) were determined by the method of Smeets
  - ETK activity was expressed in International Units (IU) per liter of sample, equivalent to the number of micromoles of glyceraldehyde-3-P formed per minute per liter
  - Erythrocyte TPP was measured using the high-performance liquid chromatography (HLPC) Warnocke method
  - Values lower than 230IU for basal ETK, higher than 1.19 for TPPE and lower than 0.17µmol, 1^{-1} for erythrocyte TPP were considered as deficient.
- *Variable Two:* Clinical assessment included body weight, diuresis, heart rate and blood pressure and breathlessness and edema assessment. Radiologic signs were assessed by chest roentgenograms.

Independent Variable

200mg thiamine given IV or IM.

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N/A

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Description of Actual Data Sample:

Initial N: N=92 potentially-relevant papers

Attrition (final N): N=10 studies included in the review.

Age:

Ethnicity:

Other relevant demographics:

Anthropometrics (e.g., were groups same or different on important measures)

Location:

Description of Actual Data Sample:

Initial N

- 70 (11 males, 24 women in HF group
- Not specified for the control group except that they were "strictly matched by sex and age for assessment of thiamine status"
- 35 for the effect of thiamine treatment on cardiac failure.

Attrition (final N)

Same as initial.

Age

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76-95 years (mean 86±3.3).

Ethnicity

Not stated.

Other Relevant Demographics

- *Anthropometrics*
  - Heart failure was due to systemic hypertension in 61%, coronary arterial disease in 50% (often a combination of both) and valvular disease in 18%
  - The cardio-thoracic value was ²0.50 (mean 0.63±0.04) and an upper zone flow redistribution was noted
  - Alveolar pulmonary edema, interstitial pulmonary edema and pleural effusions were observed in 28%, 34% and 23% of the cases, respectively
  - All patients were classified in the NYHA as either Class Three or Four.
- The patients were receiving combination therapy including digoxin, nitrates, ACE inhibitors and furosemide
- Twenty patients underwent long-term pre-admission furosemide therapy (doses 20mg to 40mg/j)
- Non heart failure patients had altered cognitive function of psychiatric disorders in 15, infection in eight, syncope and fall in eight, cancer in three and iatrogenic disease in one.

Location

Dijon, France.

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Summary of Results:

Total-C: 8/9 studies reporting Total-C as outcome were based on oatmeal. Weighted mean difference was -0.19 mmol/L (-0.30 - -0.08, P=0.0005) for oatmeal diets vs refined grain diets. Similar effect seen from 3 studies providing data at 6 wk intervention (WMD = -0.23, -0.40 - -0.05, P=0.01), but not at 4 weeks.

LDL-C:8/9 studies reporting LDL-C as outcome based on oatmeal. weighted mean difference -0.18 mmol/L (-0.28 - -0.09, P<0.0001) for oatmeal vs refined grain diets. Similar effect seen from 3 studies providing data at 6 weeks intervention (WMD = -0.25, -0.39 - -0.10, P=0.0008), but not at 4 weeks.

TAGs, HDL-C, body weight: No evidence of a difference in HDL-C on diets with oatmeal vs refined grains from outcome data from pooling at 4 weeks, 6 weeks, or all end-of-study data.

Other outcomes: insufficient evidence found to make any conclusions about effect of wholegrain on any other risk factors for CHD (FBG, insulin, insulin resistance, blood pressure).

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Summary of Results:

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Variables	Treatment Group Measures and Confidence Intervals	Control Group Measures and Confidence Intervals	Statistical Significance of Group Difference
Dependent Variable One	Cardiac failure (CF)	Non-cardiac Failure (non-CF)	Statistically significant difference between groups
Basal ETK (IU)	281±93	291±101	NS: 28.5% in each group were deficient (NL>230)
TPPE	1.11±0.07	1.11±0.05	NS: 11.5% of CF and 6% of non-CF deficient (NL<1.19)
	CF1 (baseline, vitamin supplement)	CF2 (baseline, no supplement)	
Basal ETK (IU)	279±103	288±93	NS
TPPE	1.12±0.06	1.10±0.06	NS
Erythrocyte TPP (µmol.1^{-1})	0.19±0.04	0.20±0.05	NS
Dependent Variable Two	CF1 (baseline, vitamin supplement); Day Eight	CF2 (baseline, no supplement); Day Eight	
Basal ETK (IU)	345±112 (6% deficient)	277±54 (33% deficient)	P=0.009
TPPE	1.10±0.06 (0% deficient)	1.08±0.07 (6% deficient)	P=0.015
Erythrocyte TPP (µmol.1^{-1})	0.45±0.32 (6% deficient)	0.43±0.29 (47% deficient)	P=0.026

Other Findings

- Deficiency in baseline ETK, TPPE and erythrocyte TPP was more frequent in patients with Class Four NYHA vs. those in Class Three. However, it was not a significant difference. There also was no statistical difference between the furosemide-treated group and the non-treated group for these parameters.
- At Day 15, there was improvement in clinical symptoms in 94% of the untreated group and in 65% of the treated group, but this was not a statistically significant difference (P=0.072). There was no significant improvement in the cardiothoracic value of either group. There was also no difference in the two groups in medications used
- No adverse events were mentioned.

Author Conclusion:

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There is some evidence from RCTs that wholegrain oats can reduce LDL-C and Total-C risk factors for CHD. There is a lack of trialls on other wholegrain foods and diets.

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Author Conclusion:

- A significant improvement in thiamine status was noted. However, there was no clinical improvement, compared to controls.
- Whether systematic thiamine supplementation is indicated in cardiac failure patients requires further studies.

Reviewer Comments:

see paper for data tables, search strategy

Studies included in the review included a variety of individuals

Authors state that the, analysis was based on a limited number of studies and studies of poor quality.

Reviewer Comments:

- *Small number of patients*
- *Comparison group for baseline thiamine status was also comprised of ill patients, even though the mean values were normal. Perhaps a group with healthy individuals might have had a smaller percentage who were deficient.*
- *No explanation was given for the use of either IV or IM thiamine in the experimental group.*

Reviewer Comments:

see paper for data tables, search strategy

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Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	No
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

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3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	N/A
4.1.	Were follow-up methods described and the same for all groups?	N/A
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	N/A
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	???
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A

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6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	N/A
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	N/A
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	???
10.1.	Were sources of funding and investigators' affiliations described?	No
10.2.	Was the study free from apparent conflict of interest?	???

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Research Design and Implementation Criteria Checklist: Review Articles

Relevance Questions		
1.	Will the answer if true, have a direct bearing on the health of patients?	Yes
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1.	Will the answer if true, have a direct bearing on the health of patients?	Yes
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes
3.	Is the problem addressed in the review one that is relevant to nutrition or dietetics practice?	Yes
3.	Is the problem addressed in the review one that is relevant to nutrition or dietetics practice?	Yes
3.	Is the problem addressed in the review one that is relevant to nutrition or dietetics practice?	Yes
4.	Will the information, if true, require a change in practice?	Yes
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Validity Questions		
1.	Was the question for the review clearly focused and appropriate?	Yes
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2.	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search termsused described?	Yes
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3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes
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3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes
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5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes
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6.	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes
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7.	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes
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8.	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes
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